

**IN THE UNITED STATES BANKRUPTCY COURT
FOR THE DISTRICT OF DELAWARE**

In re:
MALLINCKRODT PLC, *et al.*,
Debtors.

MALLINCKRODT PLC, *et al.*,
Plaintiffs,
v.
CITY OF ROCKFORD
Defendant.

Chapter 11
Case No. 20-12522 (JTD)
(Jointly Administered)

Adv. Pr. No. 21-50428 (JTD)
Re: Adv. D.I. 2 and 3

**Hearing Date: June 7, 2021 at
10:00 A.M. ET**

**Obj. Deadline: May 21, 2021 (By
Agreement)**

**DECLARATION OF ANTHONY L. DEWITT, ESQ. IN OPPOSITION TO PLAINTIFF'S
MOTION FOR SUMMARY JUDGMENT**

I, Anthony L. DeWitt, hereby state and declare as follows:

1. I am admitted to practice before the federal and state courts in Missouri, the United States Court of Claims, and the Fifth, Seventh and Tenth U.S. Circuit Courts of Appeal. I am a staff attorney with Bartimus, Frickleton, Robertson, Rader, PC, in Leawood Kansas.
2. I was authorized by Order of this Court [dated 2/9/21; D.I. 1332] to participate as counsel for the Acthar Plaintiffs (of which the City of Rockford is one of those parties) *pro hac vice*.
3. As part of my practice, I have represented numerous relators in Federal False Claims Act (31 USC § 3729 et seq.) lawsuits and have written and published on these cases, as well as ethical and trial preparation journal articles.
4. I make this declaration from personal knowledge and based on documents reviewed by me in my role as counsel for the Acthar Plaintiffs and City of

Rockford.

Relevant Background

5. The City of Rockford filed its case against Debtors and their co-conspirators the Express Scripts (now Evernorth) entities on April 6, 2017.

6. Rule 56(d) of the Federal Rules of Civil Procedure provides that “[i]f a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition [to the motion for summary judgment], the court may: (1) defer considering the motion or deny it; (2) allow time to obtain affidavits or declarations or to take discovery; or (3) issue any other appropriate order.”

7. The Third Circuit, interpreting this Rule, and its predecessor, Rule 56(f), in the matter of *Dowling v. City of Philadelphia*, 855 F.2d 136, 139-140 (3d Cir. 1988), has construed it as requiring that “a party seeking further discovery in response to a summary judgment motion submit an affidavit specifying, for example, what particular information is sought; how, if uncovered, it would preclude summary judgment; and why it has not previously been obtained.” *See also, Commonwealth v. Sebelius*, 674 F.3d 139, 157 (3d Cir. 2012) (following the *Dowling* case, and stating that when “a party opposing summary judgment believes that s/he needs additional time for discovery, Rule 56(d) specifies the procedure to be followed.”).

8. The Third Circuit has held that “a continuance of a motion for summary judgment for purposes of discovery should be granted almost as a matter of course” if the party opposing summary judgment files an affidavit addressing the aforementioned three requirements with specificity, and particularly when detailed information, necessary to the successful opposition to summary judgment, is in the sole possession of the moving party. *Sames v. Gable*, 732 F.2d 49, 51 (3d Cir. 1984) (*quoting Costlow v. United States*, 552 F.2d 560, 564 (3d Cir. 1977)); *see also, Banks v. City of Phila.*, 309 F.R.D. 287, 292 (E.D. Pa. 2015). This is especially true where “relevant facts are under control of the party moving for

summary judgment.” *Shelton v. Bledsoe*, 775 F.3d 554, 568 (3d Cir. 2015). A district court has discretion when deciding a Rule 56(d) motion. *See e.g., Contractors Ass’n. v. City of Phila.*, 945 F.2d 1260, 1267 (3d Cir. 1991). “Vague or general statements of what a party hopes to gain through a delay for discovery under former Rule 56(f), now Rule 56(d), are insufficient.” *Fenter v. Kraft Foods Global, Inc.*, No. 11-4916, 2012 U.S. Dist. LEXIS 163016, at *10 (E.D. Pa. Nov. 14, 2012) (citing *Hancock Indus. v. Schaeffer*, 811 F.2d 225, 230 (3d Cir. 1987)).

9. While Rule 56 (d) should be liberally construed, the party requesting a continuance must demonstrate due diligence in pursuing discovery before the filing of the summary judgment motion. *See e.g., Allstate Ins. Co. v. Century Indem. Co.*, No. 06-4373, 2009 U.S. Dist. LEXIS 102303, at *8 (E.D. Pa. Oct. 29, 2009). A showing of diligence is required because “[t]he purpose of this rule is to combat premature summary judgment motions by allowing ‘a summary judgment motion to be denied . . . if the nonmoving party has not had an opportunity to make full discovery.’” *Kosmoski v. Express Times Newspaper*, No. 08-CV-1555, 2009 U.S. Dist. LEXIS 74868, at *3 (E.D. Pa. Aug. 19, 2009) (quoting *Celotex Corp. v. Catrett*, 477 U.S. 317, 326). “In other words, the rule is intended to safeguard against judges swinging the summary judgment axe too hastily.” *Kosmoski*, 2009 U.S. Dist. LEXIS 74868, at *3 (internal citation omitted). Further, “[a] basic tenet of Fed. R. Civ. P. 56(d) is that summary judgment should be refused where the nonmoving party has not had the opportunity to discover information that is essential to his opposition.” *Asbestos Prods. Liab. Litig. v. Ford Motor Co.*, No. 09-69125, 2011 U.S. Dist. LEXIS 43658, at *6 (E.D. Pa. Feb. 22, 2011) (internal citation and quotation omitted).

10. Here, this Rule 56 (d) Declaration addresses all of these requirements. As stated herein, the particular information Rockford seeks is set forth.

11. I make this Declaration in support of Plaintiff’s request that the Court deny the Defendants’ Motion pursuant to Rule 56 (d)(1) of the Federal Rules of Civil Procedure, or enter such

other order as is just pursuant to Rule 56 (d)(3) of the Federal Rules of Civil Procedure due to the genuine issues of material fact and law in this matter, and also because the factual averments within the Defendants' Motion for Summary Judgment are contrary to the record in this case due to their refusal to acknowledge certain facts revealed through discovery in the Rockford case and other cases, including the Qui Tam cases discussed below, that would defeat their Motion.

12. The City of Rockford makes this application under Rule 56(d) without waiving its right to further oppose the Defendants' Motion for Summary Judgment on any grounds including, without limitation, its argument that, the evidence in documents and testimony already obtained raises genuine, triable issues of material fact sufficient to defeat the Defendants' Motion or that the Defendants fail as a matter of law to carry their initial threshold burden for purposes of summary judgment under Federal Rule of Civil Procedure 56 based on the numerous procedural and substantive deficiencies in their Motion, as identified in Plaintiff's opposition papers.

13. Included in the initial complaint, first amended complaint, and second amended complaint (SAC) were the following counts:

- COUNT IV - Fraud
- COUNT V - Conspiracy To Defraud/Concerted Action
- COUNT VI - Maintenance Of Monopolization Of The ACTH Market (15 U.S.C. § 2)
- COUNT VII Anti-Competitive Agreements In Unreasonable Restraint Of Trade (15 U.S.C. § 1)
- COUNT VIII - State Antitrust Law Claims
- COUNT IX - Violation of 18 U.S.C. §1962(c) (RICO)
- COUNT X - Violation of 18 U.S.C. § 1962(a) (RICO)
- COUNT XI - Violation of 18 U.S.C. § 1962(d)) (RICO)

14. The SAC was filed on December 8, 2017. A true and correct copy of the SAC is attached hereto as **Exhibit “A”**.

15. At the time the SAC was filed, several False Claims Act cases against Debtors were pending under seal in the United States District Court for the Eastern District of Pennsylvania. *See, e.g., Fourth Amended Qui Tam Complaint*, filed at Dkt. No. 40 in Case No. 2:212-cv-00175-BMS (E.D. Pa.), at **Exhibit “B”** hereto; *U.S. ex. Rel. Clark v. Questcor*, Dkt. No. 1 filed in Case No. 2:13-cv-01776-BMS (E.D. Pa.), at **Exhibit “C”** hereto.

16. In 2017, Debtors and their co-conspirators moved to dismiss the City of Rockford’s complaint, complaining that the City of Rockford had not met the pleading standard articulated in Rule 9(b) for its fraud-based claims.

17. When they filed their Motion to Dismiss, the Mallinckrodt Defendants did not disclose to the City of Rockford or the Court that they were defendants in two qui tam cases filed against them in 2012 by three former employees of Mallinckrodt, even though the company was fully aware of that fact.

18. Indeed, Debtors’ counsel at Skadden Arps was hired in 2012 to undertake an investigation into the claims of these employees, both while they still worked for the company and after they sued and left. (A collection of the Board of Directors meeting minutes reflecting Skadden lawyers advising the Debtors’ Board about the False claims act claims of the company employees was previously marked and admitted into evidence in this cases during the hearing on the Acthar Plaintiffs’ Objection to Debtors’ Retention of Skadden Arps as an ‘Ordinary Course Professional’.¹ (D.I. 1286)

¹ Due to claims of confidentiality, those exhibits will not be reproduced in this public filing, but will be re-introduced at the hearing on Debtors’ Motion for Summary Judgment.

19. The Acthar Plaintiffs' evidence presented in support of their objection to Skadden's retention details this direct knowledge on the part of the Debtors of their unlawful conduct in violation of the federal False Claims Act.

20. None of this evidence was available to the City of Rockford at the time Mallinckrodt moved to dismiss the Rockford SAC. However, it was available to Mallinckrodt.

21. Despite this direct knowledge that employees of Mallinckrodt were actively engaged in fraudulent conduct in the marketing and sales of Acthar, Mallinckrodt's lawyers argued in the Motion to Dismiss the Rockford SAC that "Plaintiffs' claim for common law fraud fails because Plaintiffs allege no facts showing a fraudulent scheme, much less with particularity." Rockford Dkt. No. 100 at 25, **Exhibit "D"** hereto.

22. Debtors further argued that "Plaintiffs have not identified: *what* the allegedly false statement are, *by whom* the statements were made, *to whom* the statements were made, *where* the statements were made, and *how* the statements were made." *Id.* at 25, n. 12 (emphasis in original).

23. Years later, in September 2019, Debtors would choose to settle, rather than contest, the False Claims Act claims of its three former employees, expressly naming a dozen employees of Mallinckrodt engaged in such fraudulent conduct. *See* Attachment "A" to September 3, 2019 Letter Agreement, attached to Settlement Agreement at Dkt. No. 74 filed in Case No. 2:12-cv-00175-BMS, at **Exhibit "E"** hereto.

24. In response to the Debtors' Motion to Dismiss the Rockford SAC, the Court undertook a comprehensive review of all the evidence and ruled on the motion to dismiss. It dismissed the Plaintiff's RICO, common law fraud and conspiracy to defraud claims, but gave leave to replead, stating:

Defendants argue that the court should not exercise its discretion and allow plaintiffs to replead for a third time. The court notes that while another amended complaint will be plaintiffs' fourth total complaint filed in this action, a subsequent complaint would be the first incident to the court's ruling on a Rule 12(b) motion. As plaintiffs requested leave to amend in their oppositions to defendants' motions to dismiss, the court will allow plaintiffs to replead to correct the deficiencies

detailed in this opinion if counsel can do so in accordance with the obligations imposed by Rule 11 of the Federal Rules of Civil Procedure.

City of Rockford v. Mallinckrodt ARD, et. al., 360 F.Supp. 3d 730, 753 n. 12 (N.D.Ill. Jan 25, 2019) (Kapala J.)²

25. Counsel for City of Rockford was prepared to meet the requirements stated and implied in the Court's ruling, specifically, giving more detail surrounding the fraud allegations as well as ensuring that it could meet its obligations under Rule 11. However, before it could undertake a redraft of the complaint, Debtors' co-conspirator filed a motion for reconsideration, which mandated additional briefing and argument, and a second opinion on May 9, 2019 refusing reconsideration. *City of Rockford v. Mallinckrodt ARD, et. al.*, 2019 U.S. Dist. LEXIS 103885 (N.D.Ill. May 3, 2019) (Kapala J.)

26. While Judge Kapala had granted 45 days to replead, there was no prejudice to the Debtors in the City not immediately repleading in that discovery was ongoing and while Rockford worked diligently researching Debtors' marketing methods.

27. Separately, on July 12, 2019, counsel for Rockford filed a class action lawsuit against Mallinckrodt ARD alleging consumer fraud, RICO and conspiracy based upon the same fraudulent scheme alleged by the federal government in the Qui Tam lawsuits. *See* Complaint filed in *Steamfitters Local Union No. 420 v. Mallinckrodt ARD at. al.*, Dkt. 1 in 2:19-cv-03047-BMS at **Exhibit "F"** hereto.

28. Then, September 4, 2019, the United States Department of Justice (DOJ) announced that drug maker Mallinckrodt agreed to settle a portion of the fraud claims against it. Mallinckrodt agreed to pay \$15.4 million to resolve claims that its predecessor Questcor Pharmaceuticals paid illegal kickbacks to doctors to induce prescriptions of Questcor's drug H.P. Acthar Gel from 2009 to

² Specifically with respect to the RICO, common law fraud and conspiracy claims the Court plainly granted leave to amend. *Id* at 774 (In order to assist the parties should plaintiffs wish to replead a RICO violation, the court will also address the issue of RICO causation."); 777 ("the grants plaintiffs leave to replead to correct the deficiencies related to these claims if plaintiffs can sufficiently do so").

2013. *See* **Exhibit “E”** hereto.

29. The Government intervened in these two whistleblower suits entitled *United States of America ex rel. Strunck et al. v. Mallinckrodt ARD, Inc.*, No. 12-CV-0175 (E.D. Pa.) and *United States of America ex rel. Clark v. Questor Pharmaceuticals, Inc.*, No. 13-CV-1776 (E.D. Pa.), alleging that at least 12 Questcor sales representatives, marketing Acthar, provided illegal remuneration to health care providers. The prohibited remuneration took the form of lavish meals and entertainment. The Government further alleged that the company provided this in-kind remuneration with the intent to induce referrals of Acthar for Medicare Beneficiaries, resulting in a violation of the Anti-Kickback Statute (AKS) and the submission of false claims to Medicare.

30. Counsel for City of Rockford incorporated that information into the other Acthar cases filed against the Debtors in Philadelphia and Tennessee, but did not seek to incorporate such facts into an amended pleading in the City of Rockford case until discovery closed in December of 2020 per the Court’s case management order. *See* Rockford Order at **Exhibit “G”** hereto.

31. Discovery was ongoing in the City of Rockford case, but was being deliberately slowed by Debtors. Although the Court in Rockford granted the City’s motion to depose the Apex defendants officers (CEO Trudeau and former CEO Fares), over Mallinckrodt’s objections, various excuses were made and the dates were put off continually until they could shift their case to this forum where they likely believed they would never have to appear for depositions. *See* emails at **Exhibit “H” and “I”** hereto.

32. The abrupt re-scheduling of these important depositions was calculated by counsel to delay the taking of this discovery until the October 12, 2020 bankruptcy filing that was known by counsel.

33. Indeed, the Statement of Work (“SOW”), signed July 1, 2020 between Debtor ST Shared Services, LLC and A&P partner (and Declarant) Michael Bernstein, expressly stated that “[t]he SOW shall govern through the end of fact discovery in the Rockford and MSP matters, which

as of the date of execution of this SOW, is scheduled to close on December 16, 2020.” A&P Exhibit 3 at AP 0000022 (marked and admitted into evidence, without objection, during the Feb. 11, 2021 hearing at 78:10-17).

34. The SOW expressly stated, “[i]n the event **Mallinckrodt plc or any of its affiliated entities enters in Chapter 11 bankruptcy prior to December 1, 2020**, as a result of which any or all of the Rockford and related antitrust/marketing litigation matters for which (A&P) has been engaged to represent Mallinckrodt are stayed, this SOW shall automatically terminate on the last day of the month during which the Chapter 11 filing occurs and the stay is entered by the bankruptcy court.” A&P Exhibit 3 at AP 0000025 (emphasis supplied).

35. Before Rockford could complete its discovery, and serve a motion for leave to amend the SAC in the Rockford case, Debtors filed for bankruptcy.

Factual Basis for Proposed Amendment

36. The specific facts alleged in Acthar Plaintiffs lawsuits on the basis of fraud and/or RICO that will be added in to the SAC in City of Rockford when leave to amend is granted, include, *inter alia*, the following facts:

- Beginning in 2007, Mallinckrodt recruited “peer-influencing physicians” (known as Key Opinion Leaders or KOLs) to present to other physicians. These presenting physicians used powerpoint presentations authored by Mallinckrodt and supplied on a laptop to the KOL, and upon completion of the presentation, that laptop was immediately returned to Mallinckrodt.
- Mallinckrodt used KOLs to:
 - (i) Conduct phony patient trials and studies on existing patient populations in order to create anecdotal “evidence” to use as a marketing ploy with other doctors at one-on-one speaker events;
 - (ii) Falsely and deceptively oversell the safety and efficacy of Acthar for unapproved uses and doses, including the 5-day “pulse therapy regimen for the treatment of multiple sclerosis, created by Dr. Staley Brod and labeled the “Brod Protocol”;
 - (iii) Fail to adequately warn of, and affirmatively mislead the medical community regarding the risks, benefits and value of Acthar; and

- (iv) Unlawfully promote Acthar for usage in populations for which it had not received FDA approval and for which the safety and efficacy had not been established through adequate clinical evidence.
- Mallinckrodt caused increased prescribing activity of Mallinckrodt's Acthar for off-label uses and doses for which Acthar was not proven to be safe, effective or useful. The scheme was accomplished through fraudulent, or false and deceptive, claims of efficacy and safety, medical usefulness, and for unlawful, off-label purposes.
- Mallinckrodt targeted primarily medical community speaking events, seminars, continuing medical education ("CME") events as well as other physician gatherings. Debtors worked with and paid leading KOLs to help create content for these speaking events.
- Mallinckrodt paid KOLs hundreds of thousands of dollars to work for it in a campaign of false marketing and promotion.
- These highly paid KOLs came from around the country and included Dr. James Tumlin (Tennessee) (sued by Acument in Tennessee), Staley Brod (Texas), Ruwani Gunawardane (Maryland), William Shaffer (Colorado), David Mandel (Ohio) and others.
- Dr. John Millichap, who treated the Rockford babies in this case, was paid thousands of dollars by Mallinckrodt in and around the time he prescribed Acthar to the Rockford patient-beneficiaries. Dr. Millichap joined with other highly-paid Mallinckrodt KOLs in publishing articles for Mallinckrodt to use in its false marketing campaign.
- The content of Mallinckrodt's marketing campaign misrepresented the safety, efficacy, and usefulness of Acthar for off-label uses, and Mallinckrodt paid these KOLs to deliver the disguised promotional messages to unsuspecting physician attendees.
- Mallinckrodt was successful in distorting and polluting the medical discourse and medical literature surrounding Acthar to such a degree that physicians and patients were rendered incapable of making objective and informed decisions concerning the appropriateness of Acthar for off-label and label-expanding usage.
- Mallinckrodt Acthar Marketing Enterprise centered on hosting numerous events where KOL doctors trained and/or approved by Mallinckrodt would falsely oversell the efficacy and safety of Acthar and would provide favorable information on the off-label use of Acthar, often under conditions where physicians would be compensated for attending the presentation.
- Mallinckrodt funded and continues to fund scores of such events between approximately 2007 to present.
- Mallinckrodt's scheme reaped significant financial gain. From 2007 to present when Mallinckrodt's revenues from the sale of Acthar soared into the millions and billions of dollars. All the while the Acthar Plaintiffs and class member third party payors

were unaware that the vast majority of Acthar prescriptions were for off-label uses. Sales of each drug have grown at a significant rate each year.

- Currently, Acthar represents over \$1 billion in revenue to Mallinckrodt.

37. In addition to these and numerous other averments directed to the use of the mails and wires so as to establish a predicate for RICO (18 U.S.C. §1962), the pleadings provided sufficient detail to meet rule 9B and a motion to dismiss was denied in the Philadelphia case with a one-line order.

38. In order to properly respond to the Summary Judgment motion filed in this adversary proceeding, City of Rockford needs the following discovery.

Discovery Needed – Depositions

1. Corporate Designee Deposition

39. City of Rockford needs to depose the person or persons at Mallinckrodt most knowledgeable about the following topics:

- a. The Debtors' corporate structure and organization, including the Debtor entities that constitute the Specialty Brands and Specialty Generics businesses, the identities of all Debtor's entities with any role in the sale or production of Acthar; the identities of all Debtor's entities with any role in the sale or production of Synacthen; responsibilities and/or obligations of each entity in Mallinckrodt organization, and the personnel responsibilities for individuals with responsibilities related to Acthar or Synacthen.
- b. The overall marketing plan developed by Questcor for Acthar.
- c. The changes made to the marketing plan developed by Questcor after assimilation into Debtors' organization.
- d. Intercompany agreements between any of Debtors' entities, related to Acthar and Synacthen, including but not limited to:

- e. manufacturing agreements;
- f. distribution agreements;
- g. the ARD Distribution Agreement;
- h. royalty agreements;
- i. licensing agreements;
- j. any intercompany transfers;
- k. R&D service agreements;
- l. intercompany transactions involving Mallinckrodt ARD LLC or revenues related to Acthar Intercompany Transfers and/or Synacthen Intercompany Transfers; and dividends paid to parents, subsidiaries, and affiliates.
- m. Any additional transfers or transactions, including intercompany transfers and transactions, involving Mallinckrodt Lux IP S.a.r.l., Mallinckrodt Pharmaceuticals Ireland Ltd., ST Operations LLC, Mallinckrodt plc, Mallinckrodt US Pool LLC, or Mallinckrodt Group S.a.r.l, or related to Acthar or Synacthen.
- n. The notes, loans, debt instruments, credit facilities, or other instruments or facilities that are secured by the assets of or guaranteed by any of Debtors' entities related to the production, marketing, sale or distribution of Acthar.
- o. Financial information relating to Acthar manufacturing and sales, including information regarding prices charged for Acthar, costs expended by the Company in connection with the production, marketing, and sales of Acthar, sales data for Acthar, and revenues, profits, losses, and associated financial data relating to Acthar.
- p. The Debtors' \$260 million CMS/DOJ/States Settlement, including the entities against whom the DOJ and CMS have claims, the value of those claims, and the treatment of those claims under the Plan.
- q. The Company's acquisition of Questcor Pharmaceuticals in 2014, including (i) the

individuals responsible for evaluating and deciding to enter into the transaction, (ii) the Company's reasons for entering into the transaction, and (iii) the Company's knowledge of Questcor's pre- merger business practices related to Acthar.

40. This discovery is necessary in order to bind the corporate entities to the fraudulent schemes alleged, defeat suggestions that the actions involved only a few select employees, and otherwise fog and diffuse the misconduct. It would preclude summary judgment by demonstrating one or more of the elements of fraud, consumer fraud, and violations of 18 U.S.C. § 1962 as well as preventing dismissal of an amended complaint for the same reasons.

2. Key Opinion Leaders

41. The City of Rockford needs to discover the names of all the Key Opinion Leaders. The City of Rockford has been able to identify the following physicians whose testimony is essential to show the elements of conspiracy, fraud, consumer fraud and material omissions. It would preclude summary judgment by demonstrating one or more of the elements of fraud, consumer fraud, and violations of 18 U.S.C. § 1962 as well as preventing dismissal of an amended complaint for the same reasons.

42. The City of Rockford needs the deposition testimony of Dr. James A. Tumlin of Tennessee who, as a KOL, published material that supported the use of Acthar off-label. In addition to his testimony as a KOL, the City of Rockford needs detailed information regarding payments made to Dr. Tumlin.

43. The City of Rockford needs the deposition testimony of Dr. Staley Brod of Texas who, as a KOL, published material that supported the use of Acthar off-label. In addition to his testimony as a KOL, the City of Rockford needs detailed information regarding payments made to Dr. Brod.

44. The City of Rockford needs the deposition testimony of Dr. William Shaffer, of Colorado who acted as a KOL for Debtors. In addition to his testimony as a KOL, the City of Rockford needs detailed information regarding payments made to Dr. Shaffer.

45. The City of Rockford needs the deposition testimony of Irene Greenhouse, PA who acted as a KOL for Debtors. In addition to her testimony as a KOL, the City of Rockford needs detailed information regarding payments made to Dr. Greenhouse.

46. The City of Rockford needs the deposition testimony of Ruwani Gunawardane, of Maryland who acted as a KOL for Debtors. In addition to his testimony as a KOL, the City of Rockford needs detailed information regarding payments made to Dr. Gunawardane.

47. The City of Rockford needs the deposition testimony of David Mandel, of Ohio who acted as a KOL for Debtors. In addition to his testimony as a KOL, the City of Rockford needs detailed information regarding payments made to Dr. Mandel.

48. The City of Rockford needs the deposition testimony of Tommasina Papa-Rugino, of New Jersey who acted as a KOL for Debtors. In addition to her testimony as a KOL, the City of Rockford needs detailed information regarding payments made to Dr. Papa-Rugino.

49. The testimony of these key opinion leaders is necessary to demonstrate that the company, through its authorized agents, used supposedly independent physicians to alter the scientific literature, promote the use of Acthar off-label in violation of FDA regulations, and conspire to defraud and actually defraud patients, physicians and third-party payors. It would preclude summary judgment by demonstrating one or more of the elements of fraud, consumer fraud, and violations of 18 U.S.C. § 1962 as well as preventing dismissal of an amended complaint for the same reasons.

3. Apex Witnesses

50. The City of Rockford received some discovery in the Illinois District Court, but was due the depositions of Trudeau and Oneil prior to the completion of discovery. Those depositions are needed and must go forward in order to respond to this motion for summary judgment. They are necessary to place before the fact-finder the numerous false and misleading statements made by these individuals in their capacity as the corporate officers of Debtors, and to demonstrate that the conduct

is ungoing and unrelenting. It would preclude summary judgment by demonstrating one or more of the elements of fraud, consumer fraud, and violations of 18 U.S.C. § 1962 as well as preventing dismissal of an amended complaint for the same reasons.

4. Whistleblowers and Sales Representatives

51. The City of Rockford needs the deposition testimony of the whistleblowers in *United States of America ex rel. Strunck et al. v. Mallinckrodt ARD, Inc.*, No. 12-CV-0175 (E.D. Pa.).

52. The City of Rockford needs the deposition testimony of the whistleblower Scott Clark in *United States of America ex rel. Clark v. Questor Pharmaceuticals, Inc.*, No. 13-CV-1776 (E.D. Pa.).

53. The City of Rockford needs the deposition testimony of Jessica Wettstein, Debtors' sales representative whose tenure began in 2007 and whose conduct in unlawful marketing of Acthar is confirmed in Attachment A to the Settlement agreement between Debtors and Department of Justice (*See Exhibit E, attached*). In addition, City of Rockford needs information regarding bonuses and other incentives promised and/or paid to Ms. Wettstein.

54. The City of Rockford needs the deposition testimony of Corrie Prato, Debtors' sales representative whose conduct in unlawful marketing of Acthar is confirmed in Attachment A to the Settlement agreement between Debtors and Department of Justice (*See Exhibit E, attached*). In addition, City of Rockford needs information regarding bonuses and other incentives promised and/or paid to Ms. Prato.

55. The City of Rockford needs the deposition testimony of Nick Brunetti, Debtors' sales representative and the person who detailed Doctor Shaffer, and whose conduct in unlawful marketing of Acthar is confirmed in Attachment A to the Settlement agreement between Debtors and Department of Justice (*See Exhibit E, attached*). In addition, City of Rockford needs information regarding bonuses and other incentives promised and/or paid to Mr. Brunetti.

56. The City of Rockford needs the deposition testimony of Curt Buttiker, Debtors' sales

representative and Key Opinion Leader Liaison, whose conduct in unlawful marketing of Acthar is confirmed in Attachment A to the Settlement agreement between Debtors and Department of Justice (*See Exhibit E, attached*). In addition, City of Rockford needs information regarding bonuses and other incentives promised and/or paid to Mr. Buttiker.

57. This testimony is necessary to prove up the individual acts of the corporate agents in furtherance of fraud, as well as their efforts to expose the fraud where applicable, and to provide proof of the requisite scienter and predicate acts under 18 U.S.C. § 1962. It would preclude summary judgment by demonstrating one or more of the elements of fraud, consumer fraud, and violations of 18 U.S.C. § 1962 as well as preventing dismissal of an amended complaint for the same reasons.

5. Other Related Witnesses

58. The City of Rockford needs the deposition testimony of Dr. Daniel M. Hartung, a medical researcher who published an article on the Journal of the American Medical Association Open Network (JAMA Open Network) that “observed a positive association between the amount of money paid to these prescribers, their prescribing intensity, and corticotropin [Acthar] expenditures in the Medicare program with a return on investment for Mallinckrodt of about 5:1.” This testimony is necessary to demonstrate the corporate rationale for the conspiracy, as well as the company’s actions with respect to Dr. Hartung’s research. It would preclude summary judgment by demonstrating one or more of the elements of fraud, consumer fraud, and violations of 18 U.S.C. § 1962 as well as preventing dismissal of an amended complaint for the same reasons.

59. The City of Rockford needs the deposition testimony of Steven Halladay, PhD, who submitted the New Drug Application for Infantile Spasm and corresponded with the FDA regarding Acthar. His testimony is necessary because his actions set the stage for the widespread use of Acthar in furtherance of the fraud, on information and belief contained false and misleading statements, and was instrumental in the success of the conspiracy. It would preclude summary judgment by demonstrating one or more of the elements of fraud, consumer fraud, and violations of 18 U.S.C. §

1962 as well as preventing dismissal of an amended complaint for the same reasons.

60. The City of Rockford needs the deposition testimony of Dr. Gary Phillips, the Senior Vice President, and President of Mallinckrodt's Autoimmune and Rare Disease Business, who told investors "[t]he one thing that you can be sure of is that the awareness and the evidence of the product will just expand dramatically over the next year." Dr. Phillips must explain this quotation and the basis for it as it goes directly to corporate knowledge and corporate oversight over the fraudulent programs. It would preclude summary judgment by demonstrating one or more of the elements of fraud, consumer fraud, and violations of 18 U.S.C. § 1962 as well as preventing dismissal of an amended complaint for the same reasons.

Discovery Needed - Documents To Be Produced

61. The City of Rockford will seek all correspondence between all KOLs and all Mallinckrodt entities. This information is necessary to prove up the relationships as well as the methods used to promote, off-label, the use of Acthar. It would preclude summary judgment by demonstrating one or more of the elements of fraud, consumer fraud, and violations of 18 U.S.C. § 1962 as well as preventing dismissal of an amended complaint for the same reasons.

62. The City of Rockford needs the documents, memoranda, and internal notes of Dr. Phillips related to Acthar. This information is necessary to prove up the methods used to promote, off-label, the use of Acthar as well as corporate oversight. It would preclude summary judgment by demonstrating one or more of the elements of fraud, consumer fraud, and violations of 18 U.S.C. § 1962 as well as preventing dismissal of an amended complaint for the same reasons.

63. The City of Rockford needs the documents, memoranda, and internal notes of Dr. Tumlin related to his work for Debtors on Acthar. This information is necessary to prove up the relationships as well as the methods used to promote, off-label, the use of Acthar. It would preclude summary judgment by demonstrating one or more of the elements of fraud, consumer fraud, and violations of 18 U.S.C. § 1962 as well as preventing dismissal of an amended complaint for the same

reasons.

64. The City of Rockford needs the documents, memoranda, and internal notes of Dr. Staley Brod related to his work for Debtors on Acthar as well as those pertaining to his recent change in employment status. This information is necessary to prove up the relationships as well as the methods used to promote, off-label, the use of Acthar. It would preclude summary judgment by demonstrating one or more of the elements of fraud, consumer fraud, and violations of 18 U.S.C. § 1962 as well as preventing dismissal of an amended complaint for the same reasons.

65. The City of Rockford needs the documents, memoranda, and internal notes of Dr. William Shaffer related to his work for Debtors on Acthar. This information is necessary to prove up the relationships as well as the methods used to promote, off-label, the use of Acthar. It would preclude summary judgment by demonstrating one or more of the elements of fraud, consumer fraud, and violations of 18 U.S.C. § 1962 as well as preventing dismissal of an amended complaint for the same reasons.

66. The City of Rockford needs the documents, memoranda, and internal notes of detail sales representatives who worked with KOLs related to Acthar including but not limited to those of Corrie Prato, Curt Buttiker, Emily Jordan, Jessica Sukanen, Jessica Wettstein, Shauna Morales Scott Clark, Nick Brunetti, Brad Rooker, Susan Stevens, John Lanning and Michael Dittbrenner. This information is necessary to prove up the relationships with the KOLs, the direction given the KOLs, the fraudulent conduct of the KOLs, as well as the methods used to promote, off-label, the use of Acthar. It would preclude summary judgment by demonstrating one or more of the elements of fraud, consumer fraud, and violations of 18 U.S.C. § 1962 as well as preventing dismissal of an amended complaint for the same reasons.

67. The City of Rockford needs the documents, memoranda, and all other documents related to Acthar sales produced to the government, formally or informally, during the pendency of *United States of America ex rel. Clark v. Questor Pharmaceuticals, Inc.*, No. 13-CV-1776 (E.D. Pa.).

This information goes to causation and damages. It would preclude summary judgment by demonstrating one or more of the elements of fraud, consumer fraud, and violations of 18 U.S.C. § 1962 as well as preventing dismissal of an amended complaint for the same reasons.

68. The City of Rockford needs the documents, memoranda, and all other documents related to Acthar sales produced to the government, formally or informally, during the pendency of *United States of America ex rel. Strunck et al. v. Mallinckrodt ARD, Inc.*, No. 12-CV-0175 (E.D. Pa.). This information goes to causation and damages. It would preclude summary judgment by demonstrating one or more of the elements of fraud, consumer fraud, and violations of 18 U.S.C. § 1962 as well as preventing dismissal of an amended complaint for the same reasons.

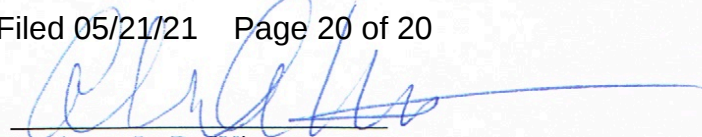
69. The City of Rockford needs the names, dates, times and locations of all CME presentations done on behalf of Debtors by KOLs so as to permit the interview of attending physicians relative to a causation analysis. This information is necessary to show the effect of the fraudulent marketing scheme on physicians of the false and misleading information spread by the KOLs and Debtors. It would preclude summary judgment by demonstrating one or more of the elements of fraud, consumer fraud, and violations of 18 U.S.C. § 1962 as well as preventing dismissal of an amended complaint for the same reasons.

Conclusion

70. Based upon the incomplete information obtained in discovery in the other Acthar Plaintiffs' cases, the several False Claims Act cases, the statements of various researchers (Dr. Hartung) and City of Rockford's counsel's fulsome appreciation of magnitude and pervasiveness of the fraud engaged in by Debtors, this discovery is necessary in order to ensure that any summary judgment motion will be properly evaluated from an evidentiary, rather than "allegation only" context as required by Rule 56.

I declare under the penalty of perjury of the laws of the United States of America that the foregoing is true and correct.

Dated: May 21, 2021



Anthony L. DeWitt
Missouri Bar # 41612